

REMARKS

The Final rejection mailed July 11, 2007, has been carefully studied. The claims in the application remain as claims 1 and 3-17, including claims 10-13 which are presently withdrawn. Applicants again respectfully submit that the claims define patentable subject matter under all the applicable statutes, and therefore they should be allowed. Favorable reconsideration, entry of the amendment presented above, and early formal allowance are all respectfully requested.

On page 6 of the last Reply (first page of the Remarks) applicants asked why claim 13 which is a hybrid product-by-process claim, is withdrawn, the bulk of the claim being directed to the structure of the product, similar to claim 1. The Final Action does not provide applicants with an answer. **Accordingly, applicants again ask why claim 13 is withdrawn when it is directed to the elected subject matter, and moreover is a linking claim.**

Claims 1, 3-9, 14 and 15 have been finally rejected under §102 as anticipated by Iida. The rejection is respectfully traversed for reasons set forth below.

This is a new rejection for claim 2 which was not amended in substance. **In other words, claim 1 as amended in the last Reply corresponds to claim 2 as previously pending.** Under these conditions, the rejection should not be Final, and applicants respectfully request withdrawal of the finality of the Office Action

of July 11, 2007, along with entry of the amendment submitted above as a matter of right. Support for this amendment appears in Fig. 4.

Claims 1, 3-9 and 14-17 are rejected as obvious<sup>1</sup> under §103 from Iida, and this rejection is respectfully traversed for the reasons of record and the additional reasons given below.

On the merits, applicants traverse the rejection for the reasons of record as set forth in the last Reply, as amplified by the comments appearing below. In the last Reply, commencing with the bottom paragraph on page 10, applicants referred to and provided a copy of an article in the name of Matsuda et al (hereinafter "Matsuda"). Applicants continue to rely on Matsuda which is part of the prior art "as a whole" and which therefore cannot be fairly ignored. Applicants consider that Matsuda clearly teaches away from use of a relatively high amount of a non-water-soluble light shielding agent such as titanium oxide. Applicants have flown in the face of the prior art as a whole, and therefore the present invention would not have been obvious to the person of ordinary skill in the art at the time the present invention was made.

As recited in claim 1, the present invention relates to a light-stabilized soft capsule formulation comprising:

a shell containing a non-water-soluble light shielding agent and having an average thickness of 200  $\mu\text{m}$  or less; and

a medicament encapsulated by said shell,

wherein the amount of the non-water-soluble light-shielding agent is 5 to 30 wt%, based on the total amount of all

components constituting the shell; and light transmittance of the shell is less than 0.6%.

One of the features of the present invention is that a capsule shell contains a relatively high amount of the non-water-soluble light-shielding agent such as titanium oxide, that is, 5-30 wt% (preferably 10-25 wt%, more preferably 15-20 wt% as recited in claims 16 and 17).

This subject matter is not disclosed in Iida and would not have been obviously deduced from Iida, since the reference teaches only a relatively small amount of the agent; and there is prior art (the aforementioned Matsuda) which teaches away from use of a relatively high amount of such light shielding agent.

In the Official Action, the rejection states in part as follows:

"Example 2 of the instant specification recites that a solution of 4 wt% titanium oxide contains 1 wt% titanium oxide. The Iida reference teaches titanium oxide up to 1.5% of the total amount of capsule shell components (see col. 3, line 23). Based on the formulation of instant Example 2, the Iida reference teaches a titanium oxide concentration of 6%,..."

However, this statement and conclusion in the Final Action are simply not correct.

Indeed, Recipe 2-1 in Example 2 in the present specification is for a shell-forming solution containing 1.0 wt% of titanium oxide (based on the total amount including water); and this

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<sup>1</sup> Applicants respectfully repeat footnote 1 from page 7 of the preceding Reply, to which applicants have received no answer from the PTO.

is processed to a shell containing 4 wt% titanium oxide (quadrupled) by removing water.

In this regard, it should be noted that a shell-forming solution is not a shell itself. In the present invention, the concentration of the non-water-soluble light-shielding agent is calculated based on the total amount of all components constituting the shell, not the material of the solution of the shell. In fact, the present specification defines the total amount as "the sum of the amounts of all capsule shell components, except for liquid (i.e., water and volatile media) added to prepare a shell-forming solution (please refer to page 20, line 4-9 of the present specification).

The same applies to Iida reference. Specifically, Iida describes in column 3, lines 25-27 as follows: "As used herein, the total amount of capsule shell components means the amount of the materials of capsule shell excluding water" (emphasis added); and describes in column 6, lines 51-54 as follows: "In Table 1 above, each value represents the charge (expressed in % by weight) of each component relative to the total amount of the materials of the shell (excluding water)" (emphasis added).

In this way, both in the present invention and in Iida reference, the amount of water is not taken into account when the concentration of the shell is calculated (that is, the concentration is calculated based on the total weight of a shell which does not include the water). The same is also true for the concentration of titanium oxide "1.5 % by weight" described in column 3, line 23 of

Iida reference. Therefore, this figure of up to 1.5% should be discussed by the figure itself, not by any converted quadrupled figure of 6%. It is absolutely clear that this figure of 1.5 wt% is not included in the range of 5-30 wt% of the present invention.

Although applicants have carefully reviewed Iida reference, applicants could not find any description which can provide a rational reason (or enable those skilled in the art) to quadruple 1.5% to 6%.

Accordingly, the present invention is not described in Iida, and is clearly novel over Iida.

For a reference, applicants calculated the concentration of titanium oxide of a shell-forming solution of Example 5 of Iida before preparing a shell. The calculated figure is about 0.5 wt% based on the total amount including water. This is almost one half of the concentration based on the total amount excluding water (1.00% according to Table 1). With regard to the amount of water and the other components, applicants relied on the conditions (e.g. 50 parts by weight of purified water) described in Example 1.

Accordingly, with no changes at all in claim 1, such claim (and all the claims which depend therefrom) define novel subject matter over Iida. The rejection based on §102 should be withdrawn for this reason alone.

Light shielding is of course inherent in the subject matter of claim 1 (and all the claims) even before the amendment proposed above. Nevertheless, as the final rejection criticizes applicants' claims in the statement "applicants are not claiming the

property of shielding<sup>2</sup> at all", applicants propose to amend claim 1 (and all the claims which depend therefrom) by incorporating the recitation "and light transmittance of the shell is less than 0.6%" into claim 1.

In the second paragraph on page 6 of the Final Action, the PTO states that even if "the property of light shielding were claimed, Figure 4 of the instant specification clearly shows light shielding with 4% titanium oxide, which is a lower concentration than that disclosed by Iida." As pointed out above, Iida simply does not disclose a concentration of titanium oxide **in the shell** as being even anywhere close to 4%.

The present invention in comparison with Iida is not a situation where the range is overlapping, or even touches at extreme ends, because the amount of titanium oxide in the Iida shell is preferably only 1%, whereas the shell in the present invention contains a minimum of 5 wt% of titanium dioxide. There is clearly no anticipation (as noted above), and there is no obviousness, because there is no reason (except the reason taught in the present specification) to even attempt to increase the titanium oxide to a level greater than the 1% (or perhaps the non-preferred maximum of 1.5%) taught by Iida. Indeed, Matsuda teaches the person of ordinary skill in the art to **not** increase the amount of titanium oxide. Applicants have flown in the face of Iida and Matsuda, and that is the very antithesis of obviousness.

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<sup>2</sup> It need not be claimed as it is inherently part of the claimed subject matter.

Stated another way, the question of obviousness may be said to reside in the question of whether a person of ordinary skill in the art would have been motivated to increase the concentration of the shielding agent to "5-30 wt%" when the prior art suggests preferably only 1 wt%. In this regard, the PTO seems to have misunderstood applicants argument at the bottom of page 11 of the last Reply. Applicant never alleged that the present invention involves the presence of titanium dioxide in an amount of 1 wt% or more; instead, applicants pointed out that even little more than 1 wt% would be unobvious, "let alone more than 5 wt%" as claimed.

Figure 4 on p.2667 of Matsuda reference shows that a degree of the decrease in the light transmittance become smaller as the titanium oxide content increases. This reduced effect can also be observed when the titanium oxide content is increased from 1% to 1.5%. Thus, those skilled in the art would not have been motivated to employ a concentration far exceeding 1.5%, as claimed according to the present invention. Matsuda is not contradictory to the description of Iida "It is preferably 1.5% by weight or less, particularly 1.0% by weight or less" in Iida. Both agree, contrary to the present invention, that there is nothing to be gained by increasing the content of shielding agent.

Withdrawal of the rejections under §§102 and 103 are in order and are respectfully requested.

All issues raised in the Final rejection are addressed above in a way which should lead to withdrawal of the rejections and allowance of the present application. Accordingly, applicants again

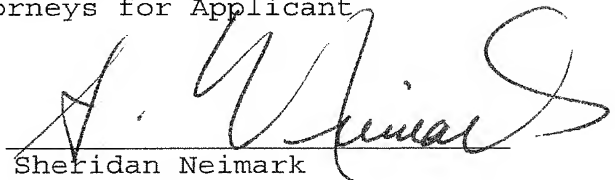
Appln. No. 10/510,644  
Amd. dated September 20, 2007  
Reply to Office Action of July 11, 2007

respectfully request favorable reconsideration, entry of the  
amendment presented above, and early formal allowance.

Respectfully submitted,

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By

A handwritten signature in black ink, appearing to read 'S. Neimark', is written over a horizontal line.

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